



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 6, 2016

Nicole O'Loughlin
Agent for Star Business Products, Inc.
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332

Subject: Label Amendment – Addition of optional marketing claims and revising directions for use for large and extra-large dogs.
Product Name: Freedom 45 Spot On for Dogs
EPA Registration Number: 75257-1
Application Date: November 2, 2015
Decision Number: 510816

Dear Ms. O'Loughlin:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

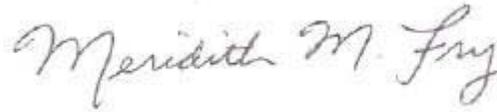
Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Meredith M. Fry". The ink is dark and the signature is centered on the page.

Meridith M. Fry, Ph.D., Product Manager 4
Invertebrate & Vertebrate Branch 1 (IVB1)
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

(Front panel - Carton Label)
(Picture of dog that is appropriate for each weight range)

ACCEPTED
Apr 06, 2016
Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 75257-1

FREEDOM 45 SPOT ON FOR DOGS

[reviewer note: Font size for word "Dog" in product name will be at least 75% the height of the largest letter in the primary brand name]

FOR USE ONLY ON DOGS OR PUPPIES 12 WEEKS OF AGE OR OLDER, WEIGHING [5-10 LBS.] [11-32 LBS.] [33-66 LBS.] [MORE THAN 66 LBS.] [5 to 10 LBS.] [11 to 32 LBS.] [33 to 66 LBS.] [OVER 66 LBS.]

DO NOT USE ON CATS – MAY BE FATAL
Keep cats away from treated dogs for 24 hours.
If applied to or ingested by a cat, contact your veterinarian immediately

[reviewer note:1.5 x 1.5 cm icon and statement will be placed on the lower right hand corner of front panel]

- [Kills, repels [and prevents re-infestation of] fleas for up to 5 weeks]
- [Kills, repels [and prevents re-infestation of] fleas for up to 4 weeks]
- [Kills, repels [and prevents re-infestation of] ticks for up to 6 weeks]
- [Kills, repels [and prevents re-infestation of] ticks for up to 4 weeks]
- [Kills, repels mosquitoes, lice and mites [on dogs] for up to 4 weeks]
- [Prevents re-infestation of fleas [on dogs] for up to 4 weeks [1 month] [30 days]]
- [Prevents re-infestation of ticks [on dogs] for up to 4 weeks [1 month] [30 days]]
- [Prevents re-infestation of fleas [on dogs] for up to 5 weeks [35 days]]
- [Prevents re-infestation of ticks [on dogs] for up to 6 weeks [42 days]]
- [Additional market claims – see last page for list of options]



ACTIVE INGREDIENT

Permethrin* (CAS# 52645-53-1).....	45.00%
OTHER INGREDIENTS	55.00%
TOTAL	100.00%

* Cis/trans ratio: max 55% [±]cis and min 45%[±]trans

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

Star Business Products
115 Green View Drive
Madison, MS 39110

EPA Registration No. 75257-1
EPA Establishment No. 75844-CA-02

Package contains a one [1], two [2],
three [3], four [4], six [6], eight [8],
twelve [12] month supply (as
applicable)

Net Contents
0.xx fl. oz. (xx ml), [1, 2, 3, 4, 6, 8, 12] x 0.xx fl. oz. (xx ml) applicators

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(Side/Back panel - Carton label)

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMAN AND DOMESTIC ANIMALS
CAUTION**

Hazards to Humans: Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before re-use.

Hazards to Domestic Animals: For external use on dogs only. Do not use on cats or animals other than dogs. Do not treat (use on) dogs or puppies less than 12 weeks of age, weighing less than 5 lbs. Consult a veterinarian before using this product on debilitated, aged, or medicated animals, pregnant or nursing pups. Consult a veterinarian before using on dogs with known organ dysfunction. Sensitivities can occur after ANY pesticide product on pets. If signs of sensitivity occur, discontinue use, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Signs of sensitivity include skin sensitivity, increased itchiness, redness, rash, hair discoloration or hair loss at the application site and lethargy.

DO NOT USE ON CATS: May be toxic or potentially fatal if applied to or ingested by cats. Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided.

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have a person sip a glass of water if able to swallow.• Do not induce vomiting unless told by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies, or pesticide concerns), you may call 1-303-389-1883 twenty four [24] hours per day, seven [7] days per week.	

ENVIRONMENTAL HAZARDS

This product is extremely toxic to aquatic organisms, including fish and invertebrates. To protect the environment, do not allow pesticide to enter or run-off into storm drains, drainage ditches, gutters or surface waters. Do not allow treated dogs to go swimming for 12 hours following treatment.

CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS

- **DO NOT USE ON CATS OR KITTENS. Do not treat cats or their bedding. This product may be toxic or potentially fatal if applied to or ingested by cats or kittens.**
- Do not apply this product to puppies less than 12 weeks of age, weighing less than 5 lbs.

Ready to use, no dilution necessary. Apply this product only as specified on this label. Do not contaminate food or feedstuff.

Do not apply more than once a month.

Do not allow your dog to ingest this product.

[reviewer note: optional graphic /photographs/images to illustrate instructions see example]



- Hold tube in upright position pointing away from user's and dog's face and body. Break off tip or cut with scissors.
- Apply [FREEDOM 45 SPOT ON FOR DOGS] [this product] by gently squeezing the applicator. Part dog's hair between shoulder blades [reviewer note: this additional text only applies to large and extra-large dogs packages: and in front of the base on the dog's tail].
- Apply specified amount of solution to the skin on the dog's back between the shoulder blades [reviewer note: this additional text only applies to large and extra-large dogs packages: and in front of the base on the dog's tail]. SEE DOSING GUIDELINES BELOW.

[pictogram of appropriate sized dog with arrow or arrows pointing where application(s) should be made]

[[puppy/toy/miniature dogs] dogs [weighing] 5-10 lbs. [5 to 10 lbs.]]

Do not apply to dogs weighing less than 5 [lbs.] [pounds]. Apply 0.75 ml of FREEDOM 45 SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades.

[[small dogs] dogs [weighing] 11-32 lbs. [11 to 32 lbs.]]

Apply 1.50 ml of FREEDOM 45 SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades.

[[large dogs] dogs [weighing] 33-66 lbs. [33 to 66 lbs.]]

Apply 1.50 ml of FREEDOM 45 SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades and 1.50 ml to the skin directly in front of the base on the dog's tail.

[[extra (ex-) large (XL) dogs] dogs [weighing] more than 66 lbs. [over 66 lbs.]]

Apply 3.0 ml of FREEDOM 45 SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades and 3.0 ml to the skin directly in front of the base on the dog's tail. Do not double-dose dogs larger than 66 lbs.

[Multi package]

[puppy/toy/miniature] dogs [weighing] 5-10 lbs. [5 to 10 lbs.] Apply 0.75 ml of FREEDOM 45 SPOT ON FOR DOGS (1 tube) to the skin of the dog's back between the shoulder blades

[small] dogs [weighing] 11-32 lbs. [11 to 32 lbs.]

Apply 1.50 ml of FREEDOM 45 SPOT ON FOR DOGS (2 tubes) to the skin of the dog's back between the shoulder blades.

[large] dogs [weighing] 33-66 lbs. [33 to 66 lbs.] Apply 1.50 ml of FREEDOM 45 SPOT ON FOR DOGS (2 tubes) to the skin of the dog's back between the shoulder blades and 1.50 ml (another 2 tubes) to the skin directly in front of the base on the dog's tail

[extra (ex-) large (XL) dogs [weighing] more than 66 lbs. [over 66 lbs.]

Apply 3.0 ml of FREEDOM 45 SPOT ON FOR DOGS (4 tubes) to the skin of the dog's back between the shoulder blades and 3.0 ml (another 4 tubes) to the skin directly in front of the base on the dog's tail. Do not double-dose dogs larger than 66 lbs.

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Side Effects: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian.



DO NOT USE ON CATS – MAY BE FATAL

Keep cats away from treated dogs for 24 hours.
If applied to or ingested by a cat, contact your veterinarian immediately

[reviewer note: 1.5 x 1.5 cm icon and statements will be placed on the lower right hand corner of front panel]

[5-10 lbs.], [5 to 10 lbs.], [Puppy/toy/miniature Dogs 5-10 lbs.], [Puppy/toy/miniature Dogs 5 to 10 lbs.]
[11-32 lbs.], [11 to 32 lbs.], [Small Dogs 11-32 lbs.] [Small Dogs 11 to 32 lbs.]
[33-66 lbs.]. [33 to 66 lbs.] [Large Dogs 33-66 lbs.] [Large Dogs 33 to 66 lbs.]
[More than 66 lbs.], [XL Dogs over 66 lbs.]

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry (preferable locked) place, away from heat or open flame, in an area that is inaccessible to children and animals.

Pesticide Disposal: Wasters resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling (tubes): If empty: Do not reuse or refill the tube. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

WARRANTY

Star Business Products warrants that this product conforms to the chemical description on the label. Star Business Products neither makes nor authorized any agent or representative to make any other warranty or fitness or merchantability, guarantee or representation, express or implied concerning this material. To the extent consistent with applicable law Star Business Products' maximum liability for breach of this warranty shall not exceed the purchase price of this product. To the extent consistent with applicable law Buyer an user acknowledge and assume all risk and liabilities resulting from handling, storage and use of this product which extend beyond the use of the product under normal conditions and in accord with statements made on the label.

Lot/Batch # _____

[Applicator Tube]

FREEDOM 45% SPOT ON FOR DOGS

PERMETHRIN INSECTICIDE 45%

KEEP OUT OF REACH OF CHILDREN

DO NOT USE ON CATS – MAY BE FATAL or Cat/Slash Icon/Graphic (representative graphic)

EPA Reg. NO. 75257-1

Read entire label before each use.

[Only for [puppy/toy/miniature] dogs [weighing] 5-10 lbs. [5 to 10 lbs.]]

[Only for [small] dogs [weighing] 11-32 lbs. [11 to 32 lbs.]]

[Only for [large] dogs [weighing] 33-66 lbs. [33 to 66 lbs.]]

[Only for [extra (ex-) large (XL) dogs [weighing] more than 66 lbs. [over 66 lbs.]]



ALTERNATIVE MARKETING CLAIMS

- Kills fleas, ticks, mosquitoes, lice, and mites [on dogs]
- Kills five [5] pests: fleas, ticks, mosquitoes, lice, and mites on dogs
- Kills five [5] different canine pests: fleas, ticks, mosquitoes, lice, and mites
- Kills five [5] different kinds of canine pests: fleas, ticks, mosquitoes, lice, and mites
- Kills five [5] different kinds of pests on dogs: fleas, ticks, mosquitoes, lice, and mites
- Kills and repels mosquitoes

FREEDOM 45 SPOT ON FOR DOGS

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